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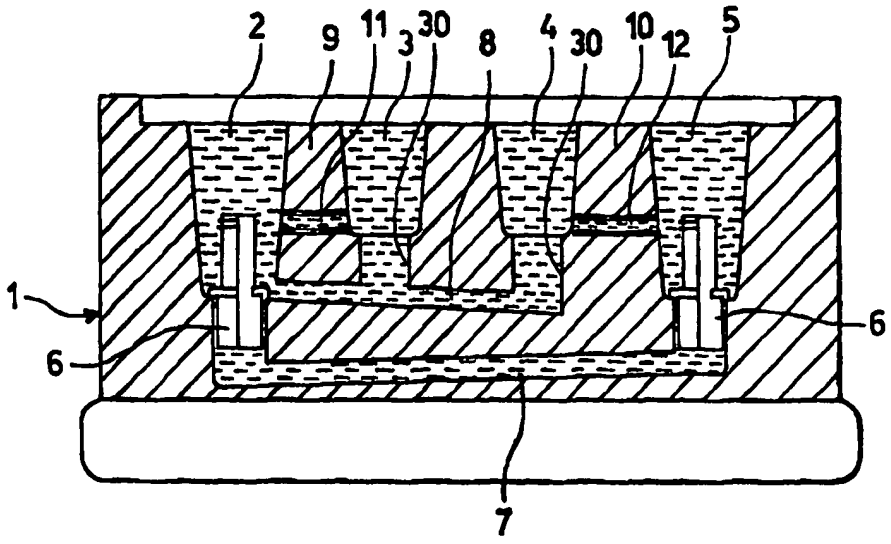

(57) Abstract

A device for the connection in a sterile environment of a peritoneal catheter, permanently attached to a patient, to a dialysis liquid drain or feed tube, characterised in that it comprises a shell (1) wherein a first and a second chamber (2, 5) are formed, suitable for being filled with a disinfecting liquid, and a connection channel (7) which connects the two chambers (2, 5) one to the other. Inside each chamber (2, 5) respective coupling means (6) are also provided for coupling, in conditions of immersion in the disinfecting liquid, to the peritoneal catheter and to the drain tube or to the feed tube, so as to form, via the connection channel (7), a sealed connection between the catheter and the drain tube or the feed tube.

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"Device for the connection in a sterile environment of a peritoneal catheter to a dialysis liquid drain or feed tube".

* * * *

The present invention relates to a device for the connection in a sterile environment of a peritoneal catheter to a tube for draining or feeding dialysis liquid.

Among the peritoneal dialysis techniques for the treatment of uraemic patients, continuous ambulatorial peritoneal dialysis (CAPD) is of great importance.

This technique, devised in 1975, consists in connecting a plastic container with approximately two litres of a dialysis liquid (a solution with added glucose normally isosmotic with plasma) to a peritoneal catheter permanently attached to the patient, by means of a short plastic tube with appropriate connectors at its two ends. After connection, the dialysis liquid fills the peritoneal cavity, where the blood which surrounds the peritoneal membrane exchanges the substances present in the aqueous phase and transfers the uraemic toxins to the dialysis liquid. After an appropriate space of time, the peritoneal cavity is emptied by connecting a drain tube to the peritoneal catheter.

For effective depuration of the patient, the aforementioned procedure has to be repeated daily at least four times during the day. This exposes the patient to the risk that, during the manoeuvres for permanent catheter connection to the drain tube first, in order to empty the peritoneal cavity of the liquid which is now full of toxins, and to the bag subsequently, so as to fill the peritoneal cavity with clean dialysis liquid, pathogenic agents may be introduced into the peritoneal cavity, causing the onset of bacterial peritonitis.

In view of the state of the art described, the object of the present invention is that of providing a device which enables the connection in a sterile environment of the peritoneal catheter to the drain tube first and to the feed tube for dialysis liquid subsequently, in order to reduce to a minimum the possibility during these operations of pathogenic agents being introduced into the peritoneal cavity.

In accordance with the present invention, this object is achieved thanks to a device for the connection in a sterile environment of a peritoneal catheter, permanently attached to a patient, to a drain tube or feed tube for a dialysis liquid, characterised in that it comprises a shell wherein a first chamber and a second chamber are formed, which chambers are suitable for being filled with a disinfecting liquid, and a connection channel which connects the two chambers one to the other. Respective coupling means are also provided in each chamber for coupling, in conditions of immersion in the disinfecting liquid, to said peritoneal catheter and said drain tube or said feed tube respectively, to form via said connection channel a sealed connection between said catheter and said drain tube or said feed tube.

Thanks to the device according to the present invention, the peritoneal catheter may be connected either to the drain tube or to the feed tube in a totally sterile environment, in that coupling of the peritoneal catheter, of the drain tube and of the feed tube to the coupling means provided in the chambers filled with disinfecting liquid takes place in conditions of immersion in the disinfecting liquid itself.

Preferably, said shell is also provided with an additional pair of chambers, also connected one to the other and to the

chambers of the first pair in order to be also filled with said disinfecting liquid, each chamber of said second pair being suitable for holding, in conditions of immersion in the disinfecting liquid, a cap for closing said peritoneal catheter and said feed tube. In this way, the operations of removing the closure caps normally provided at the ends of the peritoneal catheter and of the feed tube may be performed in a fully sterile environment.

These and other features and advantages of the present invention will be made clearer from the following detailed description of two of its embodiments, illustrated by way of non-limiting examples in the accompanying drawings, in which:

Figure 1 is a view sectioned along a vertical plane of a device according to a first embodiment of the present invention;

Figure 2 is a plan view of the device of Figure 1;

Figures 3-6 show four phases of an operation of connecting a peritoneal catheter to a bag containing a dialysis liquid;

Figure 7 is a sectioned view of a connector with which the ends of the peritoneal catheter and of a feed tube are normally provided;

Figure 8 is a sectioned view of a cap suitable for being coupled to the connector of Figure 7 to close said peritoneal catheter and said feed tube;

Figure 9 is a perspective view of a device according to a second embodiment of the present invention;

Figure 10 is a plan view of the device of Figure 9;

Figure 11 is a section along line XI-XI of Figure 10;

Figure 12 is a section along line XII-XII of Figure 10;

Figure 13 is a section along line XIII-XIII of Figure 10.

Referring to Figures 1 and 2, they show in a section along a vertical plane a first embodiment of a device for the connection in a sterile environment of a peritoneal catheter, permanently attached to a patient, to a tube for draining the dialysis liquid present in the peritoneal cavity of the patient, or to a tube for feeding clean dialysis liquid, normally contained in a bag.

The device substantially consists of a shell 1 inside whereof four chambers 2, 3, 4 and 5 are formed, substantially conical in shape. On the base of the chambers 2 and 5 two connectors 6 are stably housed, each provided with a central through hole, complementary to connectors 31 (of the so-called "luer-lok" type shown in Fig. 7) normally provided at the ends of the peritoneal catheter and of the tube for feeding dialysis liquid. In the example shown, since it is assumed that the connectors 31 placed at the ends of the catheter and of the feed tube are male connectors, the connectors 6 provided on the base of the chambers 2 and 5 are female connectors, with tubular appendage and external threading. However, should the connectors at the ends of the catheter and of the feed tube be female connectors, the connectors 6 provided on the base of the chambers 2 and 5 should be male connectors.

On the base of the shell 1, a connection channel 7 connects the chambers 2 and 5 via the through holes of the connectors 6.

The central chambers 3 and 4, which in this first embodiment have a smaller depth than the chambers 2 and 5, lead on the base to a second connection channel 8 which also flows into the chamber 2 near the base of the latter. Moreover, in the baffle 9 which separates the chambers 2 and 3 and in the baffle 10 which separates the chambers 4 and 5 two further connection

channels 11 and 12 are formed which connect the chambers 2 and 3 and the chambers 4 and 5 respectively.

All the chambers are however connected one to the other.

The two central chambers 3 and 4 are also provided, near their base, with respective seats 30 suitable for holding closure caps 32 (of the type shown in Figure 8) which can be screwed onto the connectors 31 provided at the ends of the peritoneal catheter and of the feed tube to close the latter tight.

For the use of the device described above, it is first of all necessary to fill the chambers with a disinfecting liquid, typically 100% "Amuchina" or the like. Since the four chambers 2-5 are all connected one to the other, any chamber can be chosen in which to pour the disinfectant. Filling proceeds until the level of disinfectant reaches a reference notch. This starting condition is illustrated in Figure 1; however chambers 2-5, as also all the connection channels 7, 8, 11 and 12, are filled with the disinfecting liquid.

In the following description it will be assumed that use is made of a peritoneal dialysis device of the type described in a contemporary Italian patent application in the name of the same applicant, a device which comprises a bag 12 (Figs. 3-6) containing the dialysis liquid and from which two flexible tubes 13 and 14 extend and which are connected to a portion 15 of the same bag 12 which can be separated hydraulically, for example by means of a clip 16, from the remaining of the bag 12. This dialysis device, which constitutes an improvement of the known connection system referred to as "Y-set", is merely mentioned here by way of an example, in that the connection device of the present invention can also be used with other

devices, for example the Y-set.

The first operation which the patient has to perform consists of draining the dialysis liquid present in the peritoneal cavity. For this purpose the bag portion 15 is isolated hydraulically from the remaining of the bag 12 by means of the clip 16, one (no. 14) of the two tubes which extend from the bag 12, after the respective closure cap 32 has been removed therefrom, is connected to a drain recipient 17, and the end of the other tube 13, still provided with the respective closure cap 32, is inserted by a downward movement in the chamber 3 (an operation facilitated by the conical shape of the chambers, which avoids problems of alignment) so that the cap 32 engages in the seat 30 (Fig. 3).

By acting on a handle 33 of the male connector 31 (Fig. 7) placed at the end of the tube 13, the patient makes it rotate by approximately half a turn in relation to the cap 32, which is maintained fixed in its seat 30, until the connector 31 is unscrewed from the cap 31. Then the connector 31 is inserted in the chamber 2 and is screwed onto the female connector 6 housed on the base of the latter (Fig. 4). It should be noted that the operations of unscrewing the cap 32 and screwing of the male connector 31 on the female connector 6 occur in conditions of immersion in the disinfecting liquid, and hence in a sterile environment, without the need for the patient to touch the open end of the connector 31 or to put the latter down in order to perform other operations. Neither is it necessary for the patient to wet his or her fingers with disinfectant, in that the handle 33 is sufficiently extended to project in relation to the surface of the disinfecting liquid. Once the connection has been made, both the cap 32 and the connector 31 remain

immersed in the disinfecting liquid.

Thus the device 1 is connected to a drain conduit, consisting of the tube 13, the bag portion 15 isolated from the remaining of the bag 12 and the tube 14.

At this point the patient must connect his or her peritoneal catheter to the device 1. This is carried out in a wholly similar manner to what has been described: the patient inserts the end of the catheter 18 (Fig. 5), still provided with the respective closure cap 32, in the chamber 4, so that the cap 32 is engaged in the respective seat 30 (Fig. 5).

By acting on the handle 33 of the male connector 31, the patient unscrews the latter from the cap 32 (maintained fixed in the seat 30), then inserts the connector 31 in the chamber 5 and screws it onto the female connector 6 provided on the base of the latter (Fig. 6).

In this way the catheter 18 is connected to the tube 13 via the connection channel 7.

By opening a tap 19 normally provided on the catheter 18 (typically consisting of a so-called "roller"), the operation of draining the dialysis liquid present in the peritoneal cavity of the patient begins. During this operation, the dialysis liquid to be drained empties the connection channel 7 of the disinfecting liquid.

After the draining phase, the tube 14 of the bag 12 is closed near its end connected to the bag itself, for example by means of another clip, and the bag portion 15 is reconnected to the remaining of the bag 12 (which contains the dialysis liquid) by removing the clip 16. The dialysis liquid present in the bag 12 is thus fed, via the tube 13, the channel 7 and the catheter 18, to the peritoneal cavity of the patient.

At the end of the feed phase, the patient closes the tap 19, unscrews the connector 31 of the catheter 18 from the connector 6 on the base of the chamber 5, removes it from the chamber 5, inserts it in the chamber 4, screwing it on the relevant closure cap 32, and finally removes the connector 31, with the relevant cap 32, from the chamber 4. Then, in a wholly similar manner, the patient disconnects the connector 31 of the tube 13 from the connector 6 on the base of the chamber 2, inserts it in the chamber 3, screwing it on the relevant closure cap 32, and removes everything from the chamber 3.

Figures 9-13 show a second embodiment of the connection device according to the present invention.

In this embodiment, the shell 1 of the connection device has a substantially cylindrical shape, with a widened base 50. The four chambers 2, 3, 4 and 5 are arranged in a circumferential series in the shell 1 and all have the same depth. The chambers are connected two by two thanks to connection channels 51. Moreover, the chambers 2 and 5 are connected at their base thanks to a connection channel 52 diametrical to the shell 1 and open at its two ends to facilitate the operation of emptying and washing of the connection device at the end of the dialysis operations. Two plugs 53 are also provided for closing the openings of the connection channel 52 during the dialysis operations.

As indicated by the foregoing description, the connection device of the present invention, involving operations which are performed in sequence and not simultaneously, requires the use of only one hand.

Another advantage of the device of the present invention lies in the fact that it can be reused for a theoretically

infinite number of exchanges of dialysis liquid. It thus avoids the use of expensive safety devices related to the bag assembly, which after use are thrown away together with the latter.

C L A I M S

1. Device for the connection in a sterile environment of a peritoneal catheter, permanently attached to a patient, to a drain tube or to a feed tube for a dialysis liquid, characterised in that it comprises a shell (1) wherein a first chamber (2) and a second chamber (5) are formed, suitable for being filled with a disinfecting liquid, and a connection channel (7;52) which connects the two chambers (2,5) one to the other, respective coupling means (6) also being provided in each chamber (2,5) for coupling, in conditions of immersion in the disinfecting liquid, to said peritoneal catheter and to said drain tube or said feed tube respectively, in order to make, via said connection channel (7), a tight connection between said catheter and said drain tube or said feed tube.

2. Device according to claim 1, characterised in that said connection channel (7;52) is connected to the base of the two chambers (2,5).

3. Device according to claim 2, characterised in that said connection channel (52) leads to the outside at one of its ends at least, being provided with a removable plug (53) for closing the open end of the connection channel (52).

4. Device according to claim 2, characterised in that said coupling means (6) comprise an internally hollow connector (6) which can be coupled to a complementary connector (31) provided at the end of said peritoneal catheter and of said feed and drain tubes.

5. Device according to claim 4, characterised in that the connectors (6) provided in the first and second chamber (2,5) are both female connectors which can be coupled to male connectors provided at the end of said peritoneal catheter and

of said feed and drain tubes.

6. Device according to claim 4, characterised in that the connectors (6) provided in the first and second chamber (2,5) are both male connectors which can be coupled to female connectors provided at the end of said peritoneal catheter and of said feed and drain tubes.

7. Device according to any one of claims 3-5, characterised in that it comprises a third chamber (3) and a fourth chamber (4) connected one to the other and to said first and second chamber (2,5) so as to be filled by said disinfecting liquid, said third and fourth chamber (3,4) each comprising a respective seat (30) suitable for housing, in conditions of immersion in the disinfectant, a closure cap (32) which can be coupled to said complementary connector (31) normally provided at the end of the catheter and of the feed tube to close them tight.

8. Device according to claim 6, characterised in that said third and fourth chamber (3,4) lead on the base into a second connection channel (8) which in turn leads into one of said first and second chambers (2,5).

9. Device according to claim 8, characterised in that each of said third and fourth chambers (3,4) leads into a respective one of said first and second chambers (1,5) via a respective connection channel (11, 12) formed in a respective baffle (9,10).

10. Device according to claim 7, characterised in that said first, second, third and fourth chambers (2-5) are arranged in a circumferential series and are connected one to the other and two by two via respective connection channels (51).

Fig. 1

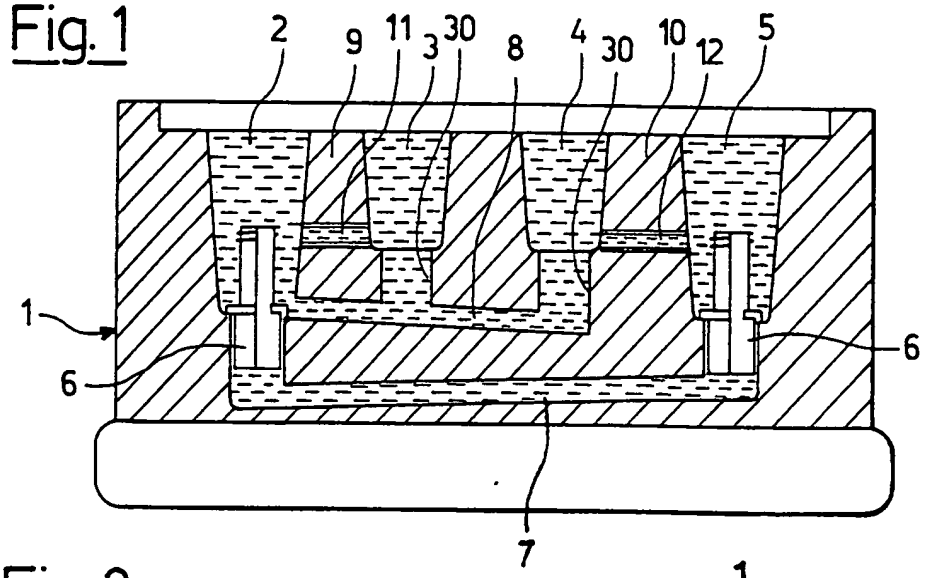


Fig. 2

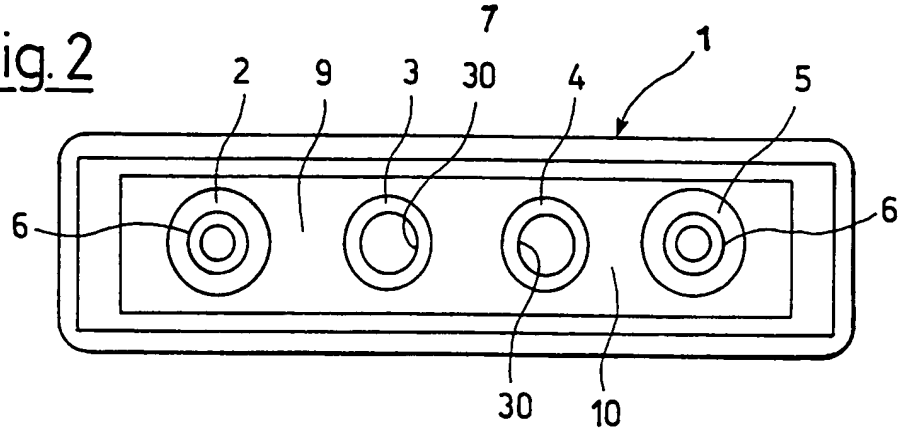
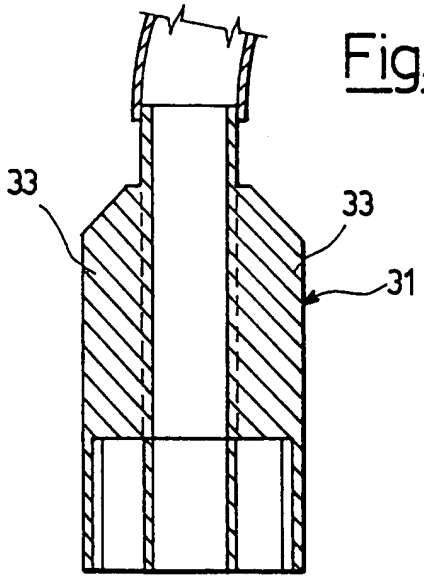


Fig. 7



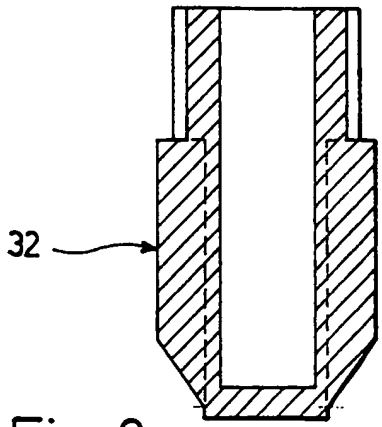


Fig. 8

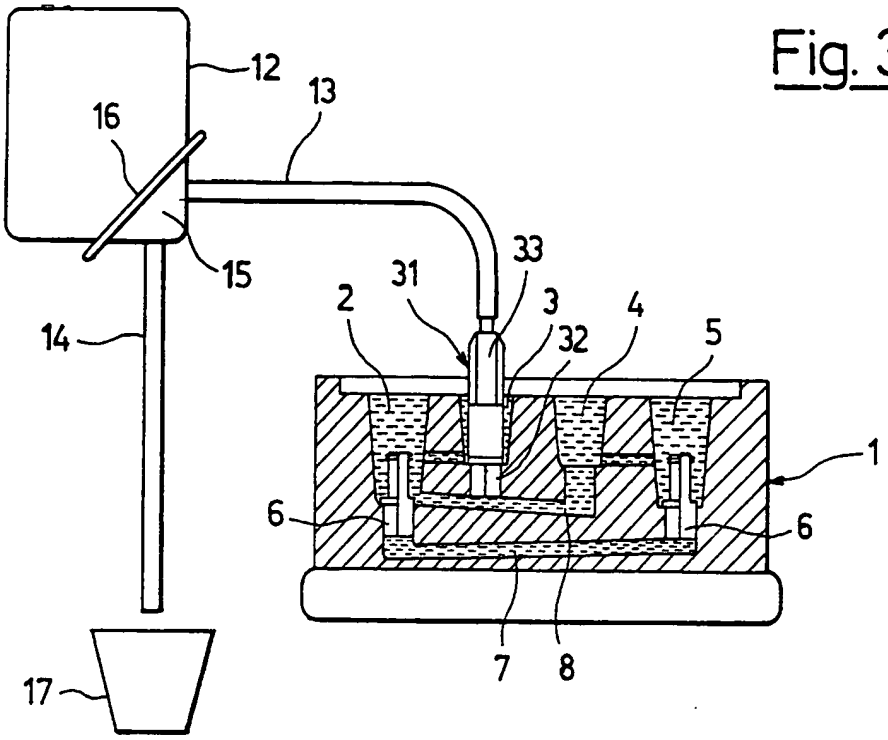

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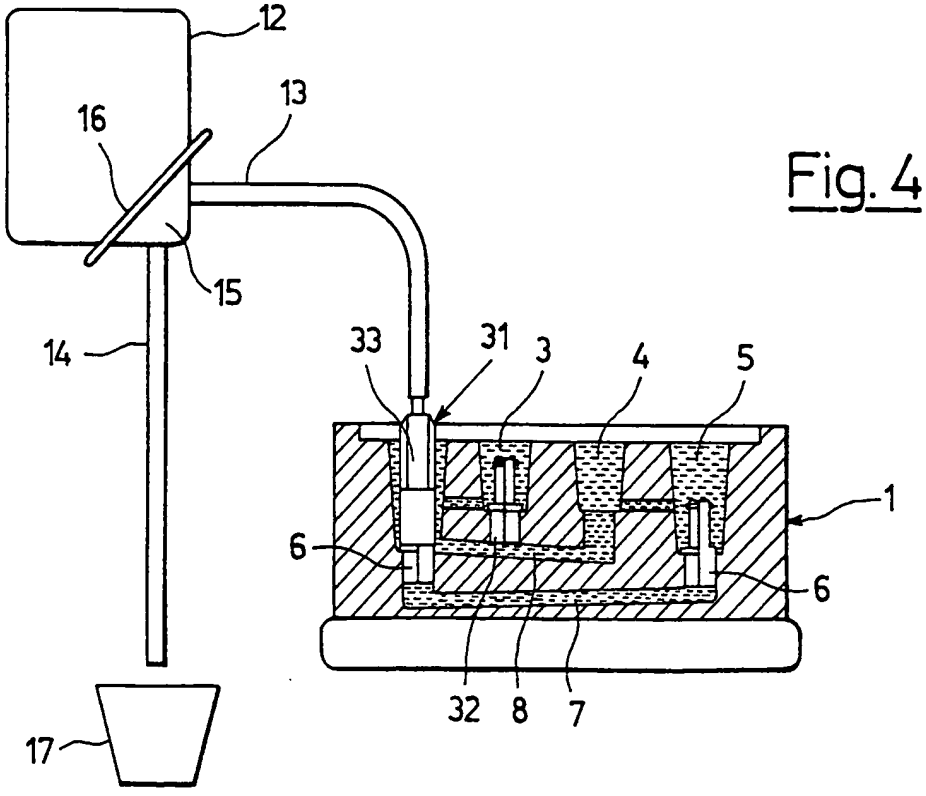
Fig. 3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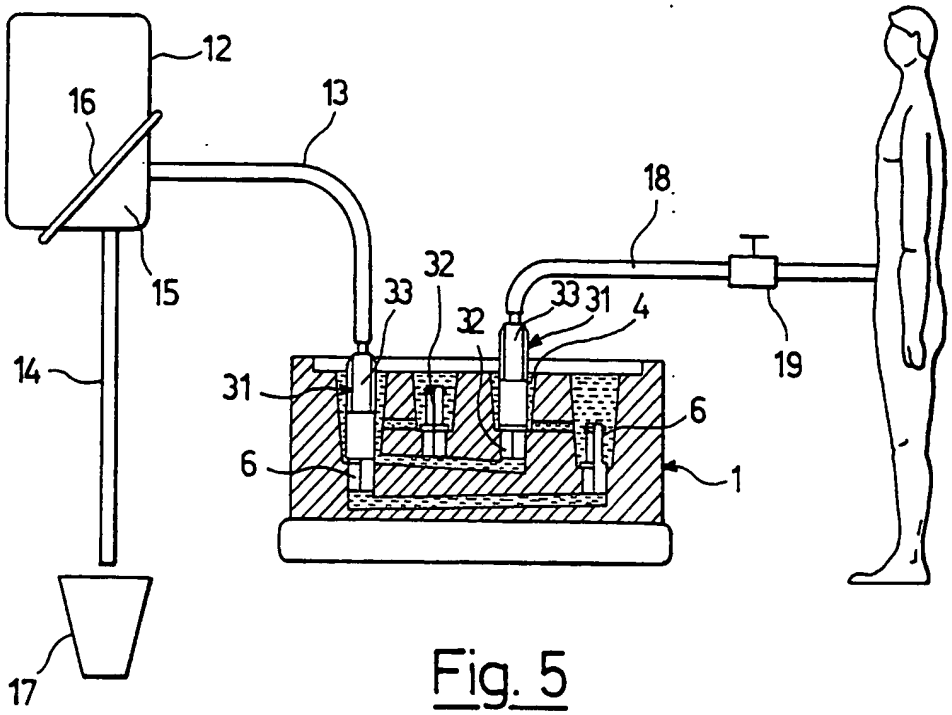
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Fig. 5

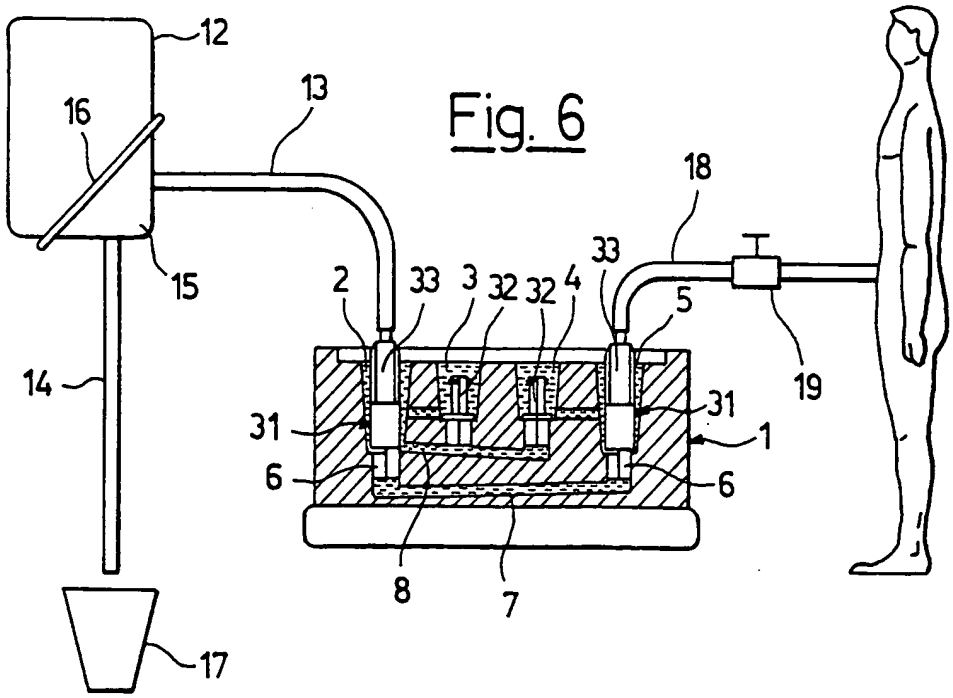
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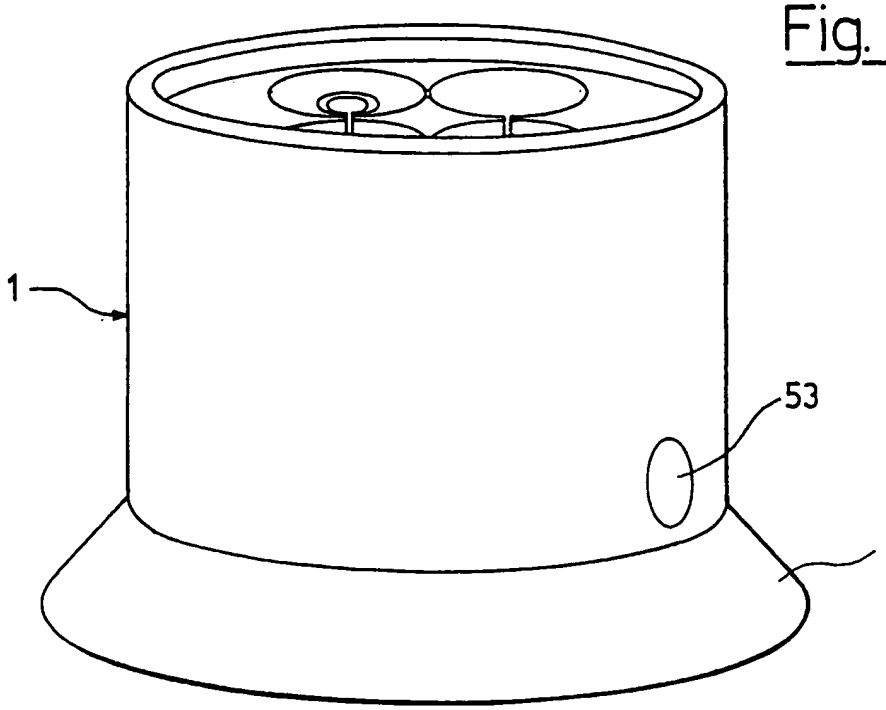
Fig. 6

Fig. 9



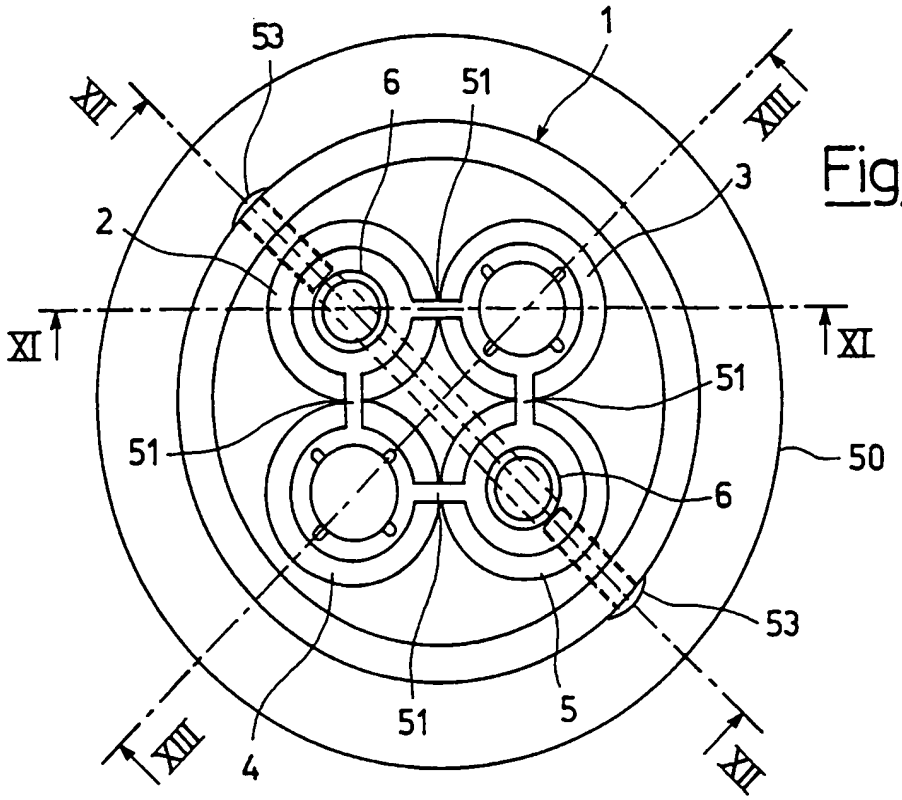


Fig. 10

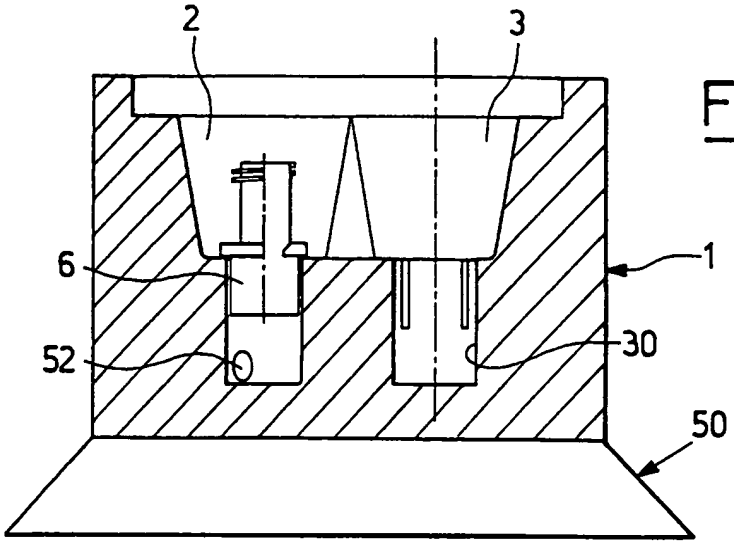


Fig. 11

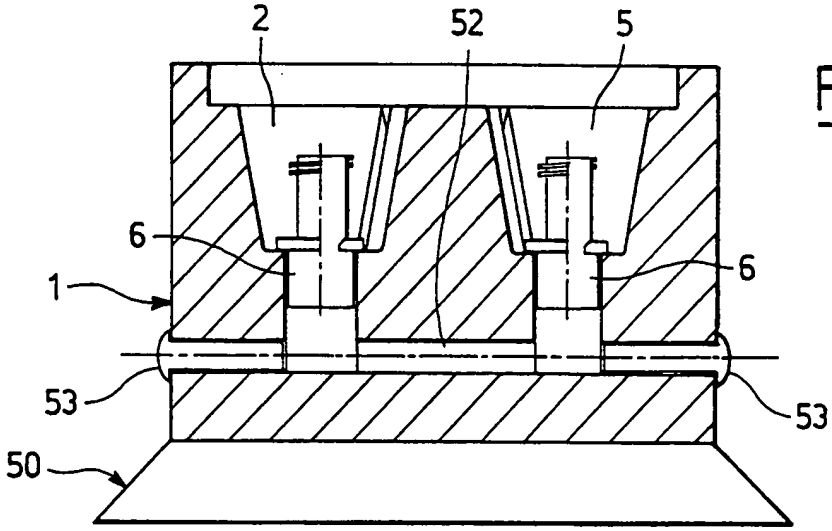


Fig. 12

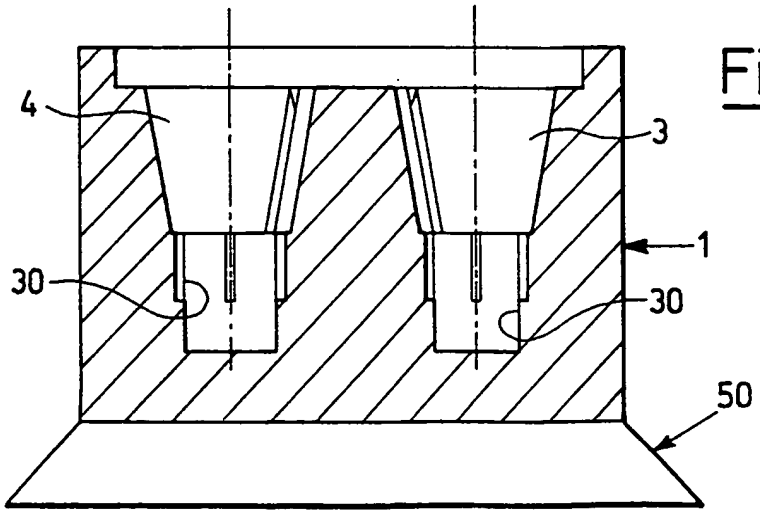


Fig. 13

INTERNATIONAL SEARCH REPORT

Intern. ·sal Application No
PCT/EP 96/02533

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M39/18 A61L2/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO,A,96 05883 (GAMBRO AB) 29 February 1996 see page 13, line 1 - page 14, line 20 see figure 11	1-4,6
A	EP,A,0 230 864 (BUONCRISTIANI) 5 August 1987 see page 7, line 13 - page 10, line 15 see figure 2	1
A	DE,A,33 47 183 (NIPPON ZEON CO. LTD) 28 June 1984 see page 10, line 9 - page 13, line 33 see figures 1-5	1

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Date of the actual completion of the international search	Date of mailing of the international search report
24 October 1996	11. 11. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Schönleben, J

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information on patent family members

Intern ..al Application No
PCT/EP 96/02533

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